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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/546,000	06/14/2006	Hirofumi Hamada	50026/054001	8449

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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
09/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/546,000	HAMADA ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 July 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *16 and 17*.
   Claim(s) withdrawn from consideration: *1-13,15,18 and 19*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633

Continuation of 11. does NOT place the application in condition for allowance because: Claims 16-17 stand rejected for reasons of record in the Office Action mailed April 25, 2008. Applicant requests reconsideration after Final Office Action.
Response to Arguments
Applicant argues that:
a) The cited prior art does not teach or suggest extraordinary gene expression in mesenchymal stem cells by a Sendai viral vector or a significant therapeutic effect on ischemia.

b) The technical effects were first achieved and recognized in the instant invention. In particular, it cannot be correct, as a general principle, that unexpected superior results exhibited in prima facie obvious inventions are necessarily latent properties which naturally flow from the invention. Therefore, the unexpected, superior results of the invention should be considered as evidence of non-obviousness.

c) The cited prior art fails to identify transfection of mesenchymal cells as a "problem", and further fails to associate improved transfection efficiency with Sendai viral vectors in particular.

Applicant's arguments have been fully considered, but are unpersuasive.
With respect to a), in response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., extraordinary gene expression or significant therapeutic effect) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, the claims are drawn to a product, wherein the mesenchymal stem cell may have any degree of gene expression, and the therapeutic composition comprising the infected mesenchymal stem cell may have any degree of therapeutic effect. Thus, the claims do not require extraordinary gene expression or significant therapeutic effect.

With respect to b), Applicant claims a composition that is a specific combination of vector (SeV), gene (Ang-1), and cell (mesenchymal stem cells). However, the prior art teaches the same combination of vector (SeV), gene (Ang-1), and cell (mesenchymal stem cells). In terms of a function, property or characteristic, the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference. A 35 U.S.C. 103 rejection is appropriate for composition claims. See In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977) and MPEP §2112. "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). In the instant case, Applicant has provided no evidence that the prior art products do not necessarily or inherently possess the characteristics of the instantly claimed product. Rather, Applicant's arguments simply iterate observations that the routineer would also achieve and observe when infecting a mesenchymal stem cell with a nucleic acid encoding Ang-1 (Ueno) using a Sendai viral vector (Sakai).

With respect to c), the cited prior art taught that foreign genes, specifically Ang-1, may be introduced into host mesenchymal stem cells using any one of a genus of viral vectors known in the art (Ueno), wherein Sendai viral vectors were recognized in the art to deliver and express said foreign genes (Sakai). Thus, those of ordinary skill in the art already recognized solutions to the problem of transfecting mesenchymal stem cells with foreign genes.